IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

D. D., a minor, by and through her parents and general guardians, LEONARD D., and HEIDI D., individually and as general guardians of D.D., Plaintiffs, vs. MEDTRONIC SOFAMOR DANEK USA, INC., and MEDTRONIC SOFAMOR DANEK, INC., Defendants.	Case No.: 2:12-cv-01222-RMG **COMPLAINT** **(Jury Trial Demanded)**

COMPLAINT

Now come the Plaintiffs, D. D., a minor, by and through Leonard D. and Heidi D., her parents, legal guardians, and next of kin, and Leonard D., and Heidi D. individually, complaining of the Defendants Medtronic Sofamor Danek USA, Inc. and Medtronic Sofamor Danek, Inc., and state and allege as follows:

PARTIES

1. Plaintiff D. D., a minor, is a resident of Johns Island, Charleston County, South Carolina.

2. Plaintiffs Leonard D. and Heidi D. are the parents and general guardians of D.D., are over 18 years of age, and are also residents of Johns Island, Charleston County, South Carolina.

3. Defendant Medtronic Sofamor Danek USA, Inc. is, upon information and belief, a Tennessee corporation with its principal place of business in Memphis, Shelby County,

Tennessee. Defendant Medtronic Sofamor Danek USA, Inc. is licensed to conduct business in the state of South Carolina and does conduct business in the state of South Carolina, including the sale and distribution of medical devices such as the device at issue in this case.

4. Defendant Medtronic Sofamor Danek, Inc., is, upon information and belief, an Indiana corporation with its principal place of business in Memphis, Shelby County, Tennessee. Upon information and belief, Defendant Medtronic Sofamor Danek, Inc. conducts business in the state of South Carolina and/or places products in the stream of commerce with the specific intent to serve the medical device market in South Carolina.

GENERAL ALLEGATIONS

5. This Court has diversity jurisdiction over this case pursuant to 28 U.S.C. §1332(a) as the amount in controversy as to each of the plaintiffs' claims against each defendant exceeds $75,000.00, and the action is between citizens of different states.

6. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a) because a substantial portion of the events giving rise to this action occurred within the geographic boundaries of the Charleston Division of the United States District Court for the District of South Carolina.

7. At all times relevant, Defendants Medtronic Sofamor Danek USA, Inc. and Medtronic Sofamor Danek, Inc. (hereinafter, collectively, "Defendants") were engaged in the business of designing, manufacturing, fabricating, assembling, inspecting, marketing, distributing, supplying, and/or selling a medical device known as the CD Horizon Spinal System.

8. At all times relevant, Defendants acted by and through their agents, servants, and/or employees. Upon information and belief, all agents, servants and employees of Defendants were acting within the course and scope of their agency and/or employment with

Defendants in performing all actions or omissions relevant to the causes of action set forth herein.

9. A stainless steel CD Horizon Spinal System device was surgically implanted into D. D.'s back on May 11, 2009, during a scheduled posterior spinal fusion procedure performed at the Medical University of South Carolina. D. D. experienced significant pain and other adverse symptoms following this posterior spinal fusion procedure.

10. Observation of certain of D. D.'s adverse symptoms subsequently led D. D.'s physicians to suspect that there had been a failure of the CD Horizon Spinal System that had been implanted in D. D.'s back.

11. On December 4, 2009, D. D. underwent another surgery at the Medical University of South Carolina Hospital to examine the condition of D. D.'s spine and the CD Horizon Spinal System that had been implanted. This surgery revealed catastrophic failure of the CD Horizon Spinal System, and D. D.'s physicians determined that this failure would require removal and replacement of the device instrumentation.

12. On December 8, 2009, D. D. underwent an additional surgery at the Medical University of South Carolina Hospital to remove and replace the instrumentation constituting the stainless steel CD Horizon Spinal System.

13. The failure of the CD Horizon Spinal System device was due to defects in the device/system that made it weaker than Defendants intended and represented. These defects existed at the time the device was distributed by Defendants or otherwise left Defendants' possession or control.

14. Specifically, the tightening of certain device screws to the recommended levels damaged the hardened surfaces of other device components, thus compromising the strength and

integrity of important device components. In addition, certain device rods were incapable of withstanding the forces present when such rods were used in certain applications contemplated by Defendants and suggested by Defendants' product literature, yet reasonable warnings of the device's limitations in that regard were never provided to D.D., her parents, or her treating physicians.

15. Upon information and belief, Defendants failed to perform testing that would simulate the actual conditions that the device would encounter following implantation. If such testing had been performed, Defendants would have been aware of the defects that existed.

16. Reasonable and feasible alternative designs for the subject device exist that would have significantly reduced or eliminated the foreseeable risks of harm presented by the above-described defects. Although Defendants knew or should have known of such reasonable and feasible alternative designs, Defendants failed to use or implement such alternatives in the design of the subject device.

17. As a result, the foreseeable risks of harm presented by the subject medical device are sufficiently great in relation to its foreseeable therapeutic benefits that a reasonable health-care provider, knowing of the foreseeable risks and therapeutic benefits, would not prescribe the subject device for any class of patients.

18. In addition, the subject medical device lacked adequate instructions and warnings, in that reasonable instructions and warnings regarding the foreseeable risks of harm were not provided to D.D., her parents, or her prescribing health care provider.

19. Specifically, D.D.'s prescribing health care provider should have been warned or instructed regarding the limitations of the subject medical device. Reasonable instructions and warnings would have notified D.D.'s prescribing health care provider that the subject device was

not reasonably safe for the application used in treating D.D., but Defendants did not provide such instructions and warnings.

20. As a direct and proximate result of Defendants' manufacture and sale of the aforementioned defective medical device, D.D. did suffer serious personal injuries and other related damages. As a further result of Defendants' conduct, D.D.'s parents Leonard D. and Heidi D. have incurred and will continue to incur substantial medical expenses for D.D's care and treatment. As Leonard D. and Heidi D. are married and have a joint and undivided interest in their daughter's care and medical treatment, these medical expenses were incurred jointly by Leonard D. and Heidi D. These medical expenses have already totaled well in excess of $150,000.00.

FOR A FIRST CAUSE OF ACTION
(Strict Products Liability – South Carolina Code §15-73-10)

21. Plaintiffs incorporate the allegations and averments of paragraphs 1 through 20 of this Complaint as though fully re-stated and set forth herein.

22. At all times relevant herein, Defendants were engaged in the business of manufacturing and selling CD Horizon Spinal System devices, and Defendants did, in fact, manufacture and sell the stainless steel CD Horizon Spinal System device that was implanted into D. D.'s back.

23. Defendants sold the CD Horizon Spinal System device that was implanted in D. D.'s back while such device was in a defective condition that rendered the device unreasonably dangerous to consumers, including D. D.

24. Defendants expected the CD Horizon Spinal System device that was implanted in D. D.'s back to reach the consumer, in this case D. D., in substantially the same condition that it was in at the time it was sold by Defendants.

25. The CD Horizon Spinal System did, in fact, reach D. D. in substantially the same condition it was in at the time it was sold by Defendants.

26. Defendants' manufacture and sale of the defective CD Horizon Spinal System device that was implanted in D. D.'s back directly and proximately caused D. D. to suffer serious personal injury and damages.

27. The injuries and damages D. D. has suffered, and continues to suffer, as a result of Defendants' conduct as aforesaid include, but are not limited to: damage to her spine and other tissues and organs, substantial pain and suffering, multiple invasive surgeries, scarring, mental and emotional distress, loss of enjoyment of life, loss of ability to carry on normal activities, related expenses, injuries, and other damages.

28. As a further direct and proximate result of Defendants' manufacture and sale of the defective CD Horizon Spinal System device that was implanted in D. D.'s back, Leonard D. and Heidi D. have incurred, and will continue to incur, substantial medical expenses and other related expenses for the care and treatment of D.D.'s injuries.

29. Defendants are therefore liable to Plaintiffs pursuant to South Carolina Code Section 15-73-10.

FOR A SECOND CAUSE OF ACTION
(Negligence)

30. Plaintiffs incorporate the allegations and averments of paragraphs 1 through 29 of this Complaint as though fully re-stated and set forth herein.

31. At all times relevant herein, Defendants had a duty to exercise reasonable care to adopt a safe design for the CD Horizon Spinal System device that was implanted in D. D.'s back.

32. At all times relevant herein, Defendants had a duty to exercise reasonable care to provide reasonable instructions and warnings regarding foreseeable risks of harm to D.D.'s prescribing and other health care providers.

33. Defendants breached these duties in one or more of the following ways:

(a) By designing, manufacturing, fabricating, assembling, inspecting, marketing, distributing, selling, and/or supplying the device in such a way that persons using it would be subjected to unreasonable danger;

(b) By failing to test the device to insure that it worked in a proper manner that was safe for consumers;

(c) By failing to provide reasonable, accurate and/or adequate warnings to D. D. and/or her parents and/or her prescribing or other treating physicians and health care providers regarding the foreseeable risks of harm posed by the device;

(d) By placing the device into the stream of commerce when Defendants knew or should have known of the defective nature of the device;

(e) By failing to employ appropriate safety mechanisms that would have limited the damage caused by the defects in the device;

(f) By failing to learn of and/or apply proper scientific and engineering principles relevant to the design, manufacture, and distribution of the device;

(g) By failing to abide by all appropriate regulatory standards for the design, manufacture, sale and/or distribution of the device; and/or

(h) By otherwise failing to exercise due care with respect to the design, manufacture, and/or distribution of the device.

34. Defendants' negligence with respect to the CD Horizon Spinal System as described above directly and proximately caused D. D. to suffer serious personal injury and damages.

35. The injuries and damages D. D. has suffered, and continues to suffer, as a result of Defendants' negligence as aforestated include, but are not limited to: damage to her spine and

other tissues and organs, substantial pain and suffering, multiple invasive surgeries, scarring, mental and emotional distress, loss of enjoyment of life, loss of ability to carry on normal activities, related expenses, injuries, and other damages.

36. As a further direct and proximate result of Defendants' negligence as aforestated, Leonard D. and Heidi D. have incurred and will continue to incur substantial medical expenses and other related expenses for the care and treatment of D.D.'s injuries.

FOR A THIRD CAUSE OF ACTION
(Breach of Warranty)

37. Plaintiffs incorporate the allegations and averments of paragraphs 1 through 36 of this Complaint as though fully re-stated and set forth herein.

38. In designing, manufacturing, advertising, marketing, and/or selling the CD Horizon Spinal System device, Defendants provided express and/or implied warranties to D. D. and her parents Leonard D. and Heidi D. that the device would be reasonably safe, merchantable, and fit for the purpose for which it was intended and used.

39. Defendants breached these warranties in that the CD Horizon Spinal System device was not reasonably safe, was not merchantable, and was not fit for the purpose for which it was intended and used.

40. As a direct and proximate result of these breaches of warranty, D. D. did suffer serious personal injury and damages.

41. The injuries and damages D. D. has suffered, and continues to suffer, as a result of Defendants' breaches of warranty include, but are not limited to: damage to her spine and other tissues and organs, substantial pain and suffering, multiple invasive surgeries, scarring, mental and emotional distress, loss of enjoyment of life, loss of ability to carry on normal activities, related expenses, injuries, and other damages.

42. As a further direct and proximate result of these breaches of warranty, Leonard D. and Heidi D. did incur substantial medical expenses and related expenses for the implantation and removal of the defective medical device and for the care and treatment of D.D.'s injuries caused by the defective medical device.

PRAYER FOR RELIEF

WHEREFORE, each Plaintiff requests that judgment be entered in his or her favor and against Defendants, jointly and severally, for both actual and punitive damages in an amount to be proven at trial in excess of Seventy-Five Thousand Dollars ($75,000.00) against each defendant, plus any and all other relief that this Court deems just and appropriate.

PLAINTIFFS DEMAND A TRIAL BY JURY.

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May 8, 2012